6/27/00
HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

M3878M

Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4769

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-61

June 21, 2000

Mr. Jack E. Hazen, President
Hillandale Farms of Florida, Inc.
P.O. Box 2109
Lake City, FL 32056-1703

Dear Mr. Hazen:

An investigation of two of your medicated feed mills located at Brown Road, Wellborn, Florida, and State Road 121 South, Lake Butler, Florida, conducted by Food and Drug Administration investigator H. Randy Bringger on May 10-11, 2000 and May 11-12, 2000 respectively, found significant deviations from Current Good Manufacturing Practices (CGMP) regulations for Medicated Feeds (Title 21, Code of Federal Regulations, Part 225). Such deviations cause feeds being manufactured at these facilities to be adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigation of your Wellborn facility found your drug inventory control to be inadequate, as it did not include a comparison of the actual versus theoretical usage when an animal drug premix was used to manufacture medicated feed. Drug lot numbers were not always recorded on the corresponding drug inventory and calculation errors were found on the drug inventory. Your mill also failed to have any written equipment clean out or sequencing procedures and actual practice consisted of returning medicated feed flush material to an ingredient bin for later use in the production of other poultry feeds. Other GMP deficiencies encountered included use of expired drug premix for medicated feed production and failure to adequately document drug premix weigh-out usage on production records for batches of medicated feed.

On May 15, 2000, we received a written request from Jerry W. Newbern, Manager of the Wellborn Mill, to withdraw the medicated feed mill license for the Wellborn mill only. This request has been forwarded to our Center for Veterinary Medicine and a copy is attached for your reference.

Our investigation of your Lake Butler facility found failure to conduct potency assays on at least three representative samples of each medicated feed containing a Category II Type A article (premix). These include Hygromycin and Oxytetracycline-Neomycin for calendar years 1999 and 2000 to date. We also found inadequate equipment clean out (sequencing) practices and written procedures that allow following any medicated feed with any non-medicated feed. For example, medicated feed containing animal drugs with specified warning statements, such as not to feed to laying chickens and withdraw from feed 14 days before slaughter of laying hens, was then followed by laying rations. Two expired drug premixes were found in stock and one was being used for medicated feed production.

Our records also show that you previously received a Warning Letter on April 11, 1994 for similar deviations from the CGMPs at the Lake Butler facility. A response dated April 20, 1994 from your Mill Manager, Robert Menzen, stated each of the listed deviations had been corrected and the mill was now in compliance with the CGMP requirements. Copies of both documents are attached for your reference.

The above is not intended as an all-inclusive list of CGMP violations. As a manufacturer of medicated and non-medicated feeds, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law.

You should take prompt action to correct these CGMP violations and establish procedures whereby such violations do not recur. Failure to promptly correct these CGMP violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure, injunction, and/or notice of opportunity for a hearing on a proposal to withdraw your medicated feed mill licenses under section 512(m)(4)(B)(ii) of the Act and 21 CFR 514.115(c)(2). This letter constitutes official notification under the law.

Based on the results of these inspections, evaluated together with the evidence before FDA when your medicated feed mill licenses were issued, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feeds are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drugs therein. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies.

You should notify this office in writing within thirty (30) working days of the receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the CGMP violations and prevent their recurrence. If corrective action cannot be completed within 30 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to Ken Hester, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, FL 32751, telephone (407) 475-4730.

Sincerely yours,

Edward R. Gilbert for

Emma R. Singleton
Director, Florida District

Enclosures
1. Letter from Jerry W. Newbern, Mill Mgr., dated May 15, 2000
2. Warning Letter dated April 11, 1994
3. Letter from Robert Menzen, Mill Mgr., dated April 20, 1994

cc: Jerry W. Newbern, Mill Manager
Hillandale Farms of Florida, Inc.
Brown Road (P.O. Box 315)
Wellborn, FL 32094

Randy R. Joyner, Mill Manager
Hillandale Farms of Florida, Inc.
S.R. 121 South
Lake Butler, FL 32054

FDA/Center for Veterinary Medicine
Office of Compliance (HFV-236)